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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/608,463 | 06/27/2003 | James W. Ryan | JR-10,003-US | 6428 |

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| EXAMINER | |
|---|---|
| SLOBODYANSKY, ELIZABETH | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/608,463 | RYAN, JAMES W. | |
| | Examiner | Art Unit | |
| | Elizabeth Slobodyansky, PhD | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-22 are pending.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 21 (all in part), drawn to a polynucleotide encoding carboxypeptidase M of SEQ ID NO: 1, including SEQ ID NO:3, a vector containing it, a host cell transformed with the same and a method of making carboxypeptidase M, classified in class 435, subclass 226.

II. Claims 1-5, 21 (all in part), drawn to a polynucleotide encoding human mouse double minute 2 homolog of SEQ ID NO: 2, including SEQ ID NO:4, a vector containing it, a host cell transformed with the same and a method of making human mouse double minute 2 homolog, classified in class 435, subclass 226.

III. Claim 6 (in part), drawn to a method of making an antibody against carboxypeptidase M, classified in class 424, subclass 185.1.

IV. Claim 6 (in part), drawn to a method of making an antibody against human mouse double minute 2 homolog, classified in class 424, subclass 185.1.

V. Claims 7, 9, 10 and 15-20 (all in part), drawn to a nucleic acid of a non-coding region of SEQ ID NO: 3, a composition, a kit and a solid support comprising thereof, classified in class 536, subclass 24.1.

VI. Claims 7, 9, 10 and 15-20 (all in part), drawn to a nucleic acid of a non-coding region of SEQ ID NO: 4, a composition, a kit and a solid support comprising thereof, classified in class 536, subclass 24.1.

VII. Claims 11 and 13 (both in part), drawn to methods of treating a subject with a polynucleotide encoding carboxypeptidase M of SEQ ID NO: 1, classified in class 514, subclass 44.

VIII. Claims 11 and 13 (both in part), drawn to methods of treating a subject with a polynucleotide encoding human mouse double minute 2 homolog of SEQ ID NO: 2, classified in class 514, subclass 44.

IX. Claims 12 and 14 (both in part), drawn to methods of treating a subject with a nucleic acid of a non-coding region of SEQ ID NO: 3, classified in class 514, subclass 44.

X. Claims 12 and 14 (both in part), drawn to methods of treating a subject with a nucleic acid of a non-coding region of SEQ ID NO: 4, classified in class 514, subclass 44.

XI. Claims 8 and 22 (both in part), drawn to a method of identifying variants of SEQ ID NO: 3, classified in class 435, subclass 6.

XII. Claims 8 and 22 (both in part), drawn to a method of identifying variants of SEQ ID NO: 4, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II as well as inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I and II, represent structurally different polynucleotides of SEQ ID NO:3 and SEQ ID NO:4 encoding structurally and functionally different polypeptides of SEQ ID NO: 1 and SEQ ID NO:2, respectively. The inventions of Groups V and VI, represent structurally different nucleic acids of non-coding region of SEQ ID NO:3 and SEQ ID NO: 4, respectively. Therefore, these inventions are drawn to nucleic acids with different structures, different effects and utilities. Further, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Inventions I and III are patentably distinct because a polypeptide used in invention III and a polynucleotide of invention I are different compounds each with its own chemical structure and function, and they have different utilities. The polynucleotide molecule of invention I is not limited in use for the production of carboxypeptidase M used in invention III but can be used as a hybridization probe in a method of invention X and carboxypeptidase M can be used for the production of an antibody in a method of invention III and in a screening assay for modulators, for example. The polynucleotide molecule of invention II is not limited in use for the production of human mouse double minute 2 homolog of SEQ ID NO: 2 used in invention IV but can be used as a hybridization probe in a method of invention XII and human mouse double minute 2

homolog of SEQ ID NO: 2 can be used for the production of an antibody in a method of invention IV and in a screening assay for modulators, for example.

Inventions I and VII as well as inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a nucleic acid of invention I and invention II can be used as a hybridization probe and in an *in vivo* method of treatment of invention VII and invention VIII, respectively, for example.

Inventions V and IX, XI as well as inventions VI and X, XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a nucleic acid of invention V can be used as a hybridization probe in an *in vitro* method of invention XI and in an *in vivo* method of treatment of invention IX. A nucleic acid of invention VI can be used as a hybridization probe in an *in vitro* method of invention XII and in an *in vivo* method of treatment of invention X.

Inventions III, IV, VII-XII are patentably distinct because they are directed to materially different methods employing different compounds such as nucleic acids and

polypeptides. Inventions VII-X and inventions XI-XII are patentably distinct because they are directed to materially different methods. Methods of inventions VII-X are *in vivo* methods while methods of inventions XI-XII are *in vitro* methods. *In vivo* and *in vitro* methods have different utilities, use different protocols and chemicals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inventions V and VI contain claims directed to the following patentably distinct species of the claimed invention: an intron, a splice junction, a 5'-non-coding region, an expression control sequence, a transcription factor binding region and a 3'-non-coding region.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7, 9, 10 and 15-20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or

to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

May 3, 2004